IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

NAZARETH HOSPITAL and	:	CIVIL ACTION
ST. AGNES MEDICAL CENTER	:	
v.	:	No. 10-3513
KATHLEEN SEBELIUS, Secretary	:	
Department of Health and Human Services	:	

MEMORANDUM

Ludwig, J. October 16, 2012

This is an action to review the decision of the Secretary of the Department of Health and Human Services dated May 17, 2012 and issued by CMS (Centers for Medicare and Medicaid Services), affirming March 23, 2010 decision of the PRRB (Provider Reimbursement Review Board). Jurisdiction: review, 42 U.S.C. § 1395oo(f)(1); federal question, 28 U.S.C. § 1331. The decision denied plaintiffs' statutory Medicare claims for serving a disproportionate share of low-income patients during 2002, known as "DSH adjustments," 42 U.S.C. § 1395ww(d)(5)(F)(vi) – Nazareth, about $249,762; St. Agnes, about $606,337.

The substantive issue is whether inpatient hospital services provided under Pennsylvania's general medical assistance program are to be counted in Medicare's DSH calculation.

Plaintiffs move for an order compelling the Secretary to produce the complete administrative record – including "the relevant, underlying rulemaking record." Pls. br., doc. no. 60 at 1; pls. mot., doc. no. 41.[1] Their argument is that they are challenging the

[1] Plaintiffs withdrew the motion's other requests. See pls. br., doc. no. 57 at 1.

"rationality" of the agency's regulation that excludes those inpatient days from the Medicare DSH computation.[2] Id.

Defendant's opposition is that to require such production "would radically expand this action and transform an ordinary challenge to an agency decision into an improper backdoor assault on the very regulation itself. . . . [Jurisdiction] "is a limited record-based review of the final administrative decision of the Secretary." Def. br., doc. no. 46 at 2, doc. no. 56 at 3-4, 6.

In addition to procedural and other opposition, defendant also reasserts: "this dispute is squarely governed by Cooper Univ. Hosp. v. Sebelius, 636 F.3d 44 (3d Cir. 2010)," def. letter Sept. 14, 2012, doc. no. 62, which affirmed the denial of a DSH adjustment for a New Jersey hospital.[3] See also def. letter Oct. 15, 2012, doc. no. 65.

After oral argument, defendant's denials of payment in this case were remanded, and

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[2] The complaint, filed July 16, 2010, contested defendant's rulemaking and adjudications. After oral argument on cross-motions for summary judgment, the matter was remanded re "whether the agency's rule-making and procedures for Medicare's 'disproportionate patient percentage' and section 1115 demonstration projects violate the rights of Pennsylvania hospitals arbitrarily and capriciously – and without a rational basis." Remand order, July 11, 2012, doc. no. 40 at 1; see also Aug. 7, 2012 supp. mem., doc. no. 47 at 2 & n.1.

[3] Our Court of Appeals upheld the Secretary's refusal to include inpatient days provided under New Jersey's Charity Care Program. Cooper Univ. Hosp. v. Sebelius, 636 F.3d 44 (3d Cir. 2010), affirming, 686 F. Supp.2d 483 (D.N.J. 2009) (Simandle, J.). Under Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 842-43 (1984), the Secretary's interpretation was held to be a permissible construction of an ambiguous statute requiring deference. Id., 686 F. Supp. 2d at 484, 489-90, 497, 498 & n.22. Cooper did not decide the questions presented here. Remand order, doc. no. 40 at 1; see FCC v. Fox Television Stations, Inc., 556 U.S. 502, 516 (2009) (constitutionality of agency action is a distinct inquiry); Bush-Quayle '92 Primary Comm., Inc. v. FEC, 104 F.3d 448, 453 (D.C. Cir. 1997) ("interpretation that would otherwise be permissible is, nevertheless, prohibited when the agency has failed to explain its departure from prior precedent").

in memorandum dated August 7, 2012 supplementing a July 25, 2012 order,[4] defendant was directed to explain "whether the agency's treatment of Section 1115 waivers as compared to Pennsylvania's state plan at the time in question was reasonable or, as plaintiffs contend, was arbitrary and capricious, and if it comported with principles of equal protection, or was constitutionally unfair." Aug. 7, 2012 supp. mem., doc. no. 47.

The issues presented by the motion for production of the rulemaking records will now be ruled on.

In this case, the Medicare statutes create a narrow but clear procedural path for review that begins with 42 U.S.C. § 1395oo. See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 10, 13 (2000) (Medicare provider's right of judicial review is strictly governed by statute). This provision allows hospitals participating in Medicare to obtain a hearing before a Provider Reimbursement Review Board as to payments received for inpatient hospital services. 42 U.S.C. § 1395oo(a), (b). The Board has "the power to affirm, modify or reverse a final determination of the fiscal intermediary with respect to a cost

[4] The July 25, 2012 order (doc. no. 44) denied without prejudice plaintiffs' request for the rulemaking records. On August 7, 2012, plaintiffs again moved that defendant be directed "to file the complete administrative record." Pls. mot., doc. no. 48 at 2-3; pls. br., doc. no. 48-1 at 3-4, 7. This motion was denied as premature. Defendant was permitted to respond to the merits of the request for the rulemaking records. Sept. 21, 2012 order, doc. no. 58. On October 5, 2012, defendant responded (doc. nos. 56, 59), and on October 11, 2012, plaintiffs replied (doc. nos. 57, 60). For jurisdictional reasons, defendant appears to refuse to produce any records – or to mediate this dispute, as requested to do in the remand order.

report." 42 U.S.C. § 1395oo(d).[5] The Board, however, has no authority to rule on certain issues, including the legality of the Secretary's regulations under the Administrative Procedures act (APA), 5 U.S.C. §§ 701-706 and the constitutional challenges presented here. See 42 U.S.C. § 1395oo(f)(1); 42 C.F.R. § 405.1867 ("Board must comply with all provisions of Title XVIII of the Act and regulations issued thereunder").[6] A decision by the Board is final unless the Secretary, on her own motion, reverses, affirms, or modifies the Board's decision. 42 U.S.C. § 1395oo(f)(1). Providers have a right to obtain judicial review by a civil action of any final decision of the Board, or any affirmation, reversal or modification by the Secretary. Id.

The Medicare Act says, in part:

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[5] "A decision by the Board shall be made upon the record made at such hearing which shall include the evidence considered by the intermediary and such other evidence as may be obtained or received by the Board, and shall be supported by substantial evidence when the record is viewed as a whole. The Board shall have the power to affirm, modify or reverse a final determination of the fiscal intermediary with respect to a cost report and to make any other revisions on matters covered by such cost report . . . even though such matters were not considered by the intermediary in making such final determination." 42 U.S.C. § 1395oo(d).

[6] "Providers shall also have the right to obtain judicial review of any action by the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines (on its own motion or at the request of a provider . . .) that it is without authority to decide the question, by a civil action . . . ." 42 U.S.C. § 1395oo(f)(1); see also 42 C.F.R. § 405.1842 (expedited judicial review). Plaintiffs did not ask the Board to certify its lack of authority to decide the APA and constitutional issues presented here, choosing instead to present those issues directly to the CMS Administrator on "own motion" review. At this stage, plaintiffs specifically asserted those issues. There was no waiver. Even under the scope of judicial review proposed by defendant, see def. letter Oct. 15, 2012, doc. no. 65 (citing Nichole Med. Equip. & Supply, Inc. v. TriCenturion, Inc., No. 11-2132, 2012 WL 4017485, at *7 (3d Cir. Sept. 13, 2012) (§ 405(g): "presentation of *any* claim to the Secretary" required) (emphasis in original)), the APA and constitutional issues were in fact presented to the agency. See, e.g., pls. final position papers to Board, AR 204, 631; pls. comments to CMS Administrator, AR 17-21, 19-20.

> provisions of . . . subsections (a), (d), (e), (h), (i), (j), (k), and (*l*) of section 405 of this title, shall also apply with respect to this subchapter [XVIII, Medicare] to the same extent as they are applicable with respect to subchapter II of this chapter [Social Security Act], except that, in applying such provisions with respect to this subchapter, any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

42 U.S.C. § 1395ii. Pertinently, this statute makes a related provision of the Social Security Act, 42 U.S.C. § 405(h), applicable to the Medicare Act "to the same extent as" it applies to the Social Security Act. Illinois Council, 529 U.S. at 8, 13. Section 405(h) says, in part:

> the findings and decision of the [Secretary] after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against . . . the [Secretary], or any officer or employee thereof shall be brought under section 1331 . . . of Title 28 to recover on any claim arising under this subchapter.

42 U.S.C. § 405(h). Section 405(h) "channels most, if not all, Medicare claims through this special review system." Illinois Council, 529 U.S. at 8; Dist. Hosp. Partners, L.P. v. Sebelius, 794 F. Supp. 2d 162, 166 (D.D.C. 2011) (§ 1395ii "generally forecloses other avenues of review by incorporating § 405(h) of the Social Security Act").

"Section 405(h) purports to make exclusive the judicial review method set forth in § 405(g)." Illinois Council, 529 U.S. at 10 (quoting 42 U.S.C. § 405(h) ("[no findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided")). However, the scope of the phrase "except as herein provided" is left unclarified. While 42 U.S.C. § 1395ii expressly incorporates and makes

subsection (h) of § 405 applicable to the Medicare Act, it does not list subsections (b) and (g) of § 405 as applicable to the Medicare Act. Instead, § 1395ii expressly refers to subsection (a) of § 405, which gives the Secretary

> full power and authority to make rules and regulations and to establish procedures, not inconsistent with the provisions of this subchapter, which are necessary and appropriate to carry out such provisions, and shall adopt reasonable and proper rules and regulations to regulate and provide for the nature and extent of the proofs and evidence and the method of taking and furnishing the same in order to establish the right to benefits hereunder.

42 U.S.C. § 405(a). The Secretary has promulgated such rules, 42 C.F.R. §§ 405.1801-1889. See id. 405.1835-1877 (rules pertinent to PRRB determinations and appeals). In particular, § 405.1877[7] expressly implements judicial review under § 1395oo(f)(1). Accordingly, the specific method for judicial review set forth by § 405.1877 governs, and subsections (b) and (g) of 42 U.S.C. § 405 are not operative here.

Defendant Secretary contends that under 42 U.S.C. § 1395oo(f)(1), judicial review is restricted to the final administrative decision of the Secretary, which precludes consideration of the rulemaking records for the amended Medicare DSH regulation. See, e.g., def. br., doc. no. 46 at 1, 3; def. br., doc. no. 56 at 4; see also def. letter Oct. 15, 2012, doc. no. 65. Defendant cites 42 U.S.C. § 405(g) and Grant v. Shalala, 989 F.2d 1332, 1338 (3d Cir. 1993). See e.g., def. br., doc. 46 at 3; def. mot. & br. in support of summary

[7] "Notwithstanding . . . any other provision of law, sections 205(h) [42 U.S.C. § 405(h)] and 1872 [42 U.S.C. § 1395ii] of the Act provide that a decision or other action by a reviewing entity is subject to judicial review solely to the extent authorized by section 1878(f)(1) [42 U.S.C. § 1395oo(f)(1)] of the Act. This section . . . implements section 1878(f)(1) [§ 1395oo(f)(1)] of the Act." 42 C.F.R. § 405.1877(a)(1).

judgment, doc. no. 21 at 14-15, 40-42. However, Grant does not support defendant's position because it concerned a different question under a much different statute – namely, whether 42 U.S.C. § 405(b) and (g) precluded a district court from conducting a trial and making independent findings of fact in an action brought by an individual under § 405 for Social Security disability benefits. Here, neither § 405(b) nor (g) is implicated because those provisions are not made applicable to the Medicare Act by 42 U.S.C. § 1395ii. Moreover, Grant was an action brought by an individual for social security disability benefits. This case involves an appeal by a Medicare provider for review of the Administrator's affirmation of the Board's determination to deny payments for inpatient hospital costs. Here, 42 C.F.R. § 405.1877 – "Provider Reimbursement Determinations and Appeals" – sets forth the method for review.

Here, the Secretary's reimbursement decisions are reviewed under the standards of the APA, 5 U.S.C. §§ 701-706.[8] Under the APA, "we 'hold unlawful and set aside agency action, findings, and conclusions' that are found to be 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." CBS Corp. v. FCC, 663 F.3d 122, 137

[8] The action of governmental authority, including HHS, is subject to judicial review except where there is a statutory prohibition or where agency action is committed to agency discretion by law. 5 U.S.C. § 701; see also id. § 702 ("person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof"); id. § 703 ("form of proceeding for judicial review is the special statutory review proceeding relevant to the subject matter in a court specified by statute"); id. § 704 ("[a]gency action made reviewable by statute . . . [is] subject to judicial review [and a] preliminary, procedural, or intermediate agency action or ruling . . . not directly reviewable is subject to review on the review of the final agency action"). But see 42 C.F.R. § 405.1877(a)(4) (if the Administrator "timely . . . affirms . . . one of the Board decisions . . . , the Administrator's . . . affirmation . . . is the only decision subject to review under section 1878(f)(1) of the Act [42 U.S.C. § 1395(f)(1)").

(3d Cir. 2011) (quoting 5 U.S.C. § 706(2)(A)), cert. denied, 132 S. Ct. 2677 (June 29, 2012); Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Ins. Co., 463 U.S. 29, 41 (1983) (§ 706(2)(A) governed agency standards promulgated under the informal rulemaking procedures of § 553 of the APA).

"The scope of review under the 'arbitrary and capricious' standard, is 'narrow, and a court is not to substitute its judgment for that of the agency.'" CBS Corp., 663 F.3d at 137 (quoting State Farm, 463 U.S. at 43). "Nevertheless, the agency must reach its decision by 'examin[ing] the relevant data,' and it must 'articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" Id. (quoting State Farm (quoting Burlington Truck Lines, Inc. v. United States, 371 U.S. 156, 168 (1962)); NVE, Inc. v. HHS, 436 F.3d 182, 190 (3d Cir. 2006) ("must ensure only that the agency has applied the procedures for rulemaking required by law and reached a rational conclusion").[9]

The scope of review of constitutional questions is "more searching." CBS Corp., 663

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[9] Our Court of Appeals has generally found agency action to be arbitrary and capricious where

> the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it would not be ascribed to a difference in view or the product of agency expertise. The reviewing court should not attempt itself to make up for such deficiencies; we may not supply a reasoned basis for the agency's action that the agency itself has not given.

CBS Corp. v. FCC, 663 F.3d 122, 137 (3d Cir. 2011), cert. denied, 132 S. Ct. 2677 (June 29, 2012) (quoting State Farm, 463 U.S. at 43) (citing SEC v. Chenery Corp., 332 U.S. 194, 196 (1947)).

F.3d at 137. The APA "separately provides for setting aside agency action that is 'unlawful,' 5 U.S.C. § 706(2)(A), which of course includes unconstitutional action. . . . [T]hat is the only context in which constitutionality bears upon judicial review of authorized agency action."[10] FCC v. Fox Television Stations, Inc., 556 U.S. 502, 516 (2009). However, HHS has no special expertise to resolve equal protection claims. See Petruska v. Gannon Univ., 462 F.3d 294, 308-09 (3d Cir. 2006) ("as a general rule, an administrative agency is not competent to determine constitutional issues" and "we are aware of no authority that requires a [party] to proffer every possible defense or legal argument before the EEOC, much less to raise all constitutional challenges"), cert. denied, 550 U.S. 903 (2007).

In cases involving issues of equal protection of the laws, "we must consider the facts and circumstances behind the law, the interests which the State claims to be protecting, and the interests of those who are disadvantaged by the law." Biener v. Calio, 361 F.3d 206, 214 (3d Cir.), cert. denied, 543 U.S. 817 (2004) (Nygaard, J.) (citation and internal quotation marks omitted). Equal protection "keeps governmental decisionmakers from treating differently persons who are in all relevant respects alike." Nordlinger v. Hahn, 505 U.S. 1, 10 (1992); FCC v. Beach Commc'n, 508 U.S. 307, 313-14 (1993) (primary inquiry under both the Fourteenth and Fifth Amendments is whether there is a rational basis for the challenged classification).

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[10] Under the APA's standards, 5 U.S.C. § 706(2)(A), whether an agency's action was arbitrary or capricious is a separate question from whether the action may be set aside as "unlawful" because it is unconstitutional. See Fox Television, 556 U.S. at 516 ("its lawfulness under the Constitution is a separate question to be addressed in a constitutional challenge").

The APA requires a reviewing court to consider "the whole record or those parts of it cited by a party." 5 U.S.C. § 706; Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 420 (1971) ("the full administrative record that was before the Secretary at the time he made his decision"); Am. Iron & Steel Inst. v. EPA, 568 F.2d 284, 296 (3d Cir. 1977) ("touchstone" of review "both as to the Agency's consideration of the issues and the factual predicates of this consideration must be the administrative record"); Dist. Hosp. Partners, 794 F. Supp. 2d at 171 (review of agency's record for the rule-making proceeding that set payments to Medicare providers for costly or lengthy hospital stays was necessary to determine whether the Secretary's methodology was arbitrary and capricious); Walter O. Boswell Mem'l Hosp. v. Heckler, 749 F.2d 788, 792 (D.C. Cir. 1984) ("court . . . should have before it neither more nor less information than did the agency when it made its decision").

Plaintiffs contend that in promulgating the Medicare DSH rules, the Secretary departed from the strict requirement set by PM A-99-62 that reimbursements would be made only for hospital services furnished to inpatients who were eligible for Medicaid. See, e.g., pls. br. in support of summary judgment, doc. nos. 24 & 25 at 12-16. They submit that the Secretary's reasons for doing so are highly relevant here – that is, applying the Medicare DSH regulation less favorably for Pennsylvania hospitals treating general assistance patients through a CMS approved state plan than for hospitals in section 1115 waiver states treating patients through approved demonstration projects. Plaintiffs cite the Secretary's acknowledgment that the disparate treatment "does advantage States that have a section 1115

expansion waiver in place . . . ." Final rule, 65 Fed. Reg. 47054, 47087 (Aug. 1, 2000) (agency "received 11 public comments on the inclusion of Section 1115 waiver days in the Medicare disproportionate share adjustment calculation").[11]

Our Court of Appeals instructs that "an agency must be afforded great latitude to change its policies, but it must justify its actions by articulating a reasoned analysis behind the change." CBS Corp., 663 F.3d at 145 (quoting State Farm, 463 U.S. at 42-43 ("agency changing its course by rescinding a rule is obligated to supply a reasoned analysis for the change")). Furthermore, "an agency cannot ignore a substantial diversion from its prior policies." Id. (citing Ramaprakash v. FAA, 346 F.3d 1121, 1124 (D.C. Cir. 2003) (agency "must provide a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored") (citation and internal quotation marks omitted)). Importantly, an "agency's obligation to supply a reasoned analysis for a policy departure requires an affirmative showing on record." Id.

Here, the Secretary acknowledges that "she might have been required to produce the full and complete rulemaking record for either of the regulations plaintiffs have identified, if this action did, in fact, properly include a challenge to either one of those regulations." Def. br., doc. no. 46 at 2 (citing Boswell Mem'l Hosp., supra) (emphasis in original omitted). Her view is that plaintiffs have not challenged those regulations.

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[11] "Several commenters were concerned with the inclusion . . . of expansion waiver days in the Medicaid portion of the Medicare DSH adjustment calculation. States without a Medicaid expansion waiver in place believed that States that did have a Medicaid expansion waiver in place received an unfair advantage. . . . [C]omments from Pennsylvania hospitals supported the continued inclusion of general assistance days in the Medicaid portion of the Medicare DSH adjustment calculation as well as expansion waiver days." 65 Fed. Reg. 47054, 47086 (Aug. 1, 2000).

The Secretary's position is not tenable. Review of the administrative record as well as the filings in this litigation[12] demonstrate that plaintiffs timely challenged the Medicare DSH rules and amended regulation – as was previously ruled. See July 11, 2012 order, doc. no. 40 at 1; see also Aug. 7, 2012 supp. mem., doc. no. 47 at 2 & n.1. In addition, the agency's reasons for promulgating the amended Medicare DSH rules are at issue here. Both the public comments and the Secretary's responses in the notice-and-comment proceedings leading to those rules are relevant.[13]

Plaintiffs are entitled to the complete administrative record, including the record made on the remand of this case. See 42 C.F.R. § 405.1865 ("Administrator must maintain a complete record of all proceedings in each appeal"). It also includes the agency's records during the notice-and-comment procedure for the interim final rule, 65 Fed. Reg. 3136 (Jan. 20, 2000) and the final rule, 65 Fed. Reg. 47054 (Aug. 1, 2000), which led to promulgation of the amended regulation implementing the Medicare DSH statute, 42 C.F.R. § 412.106(b)(4) (2000).

BY THE COURT:

/s/ Edmund V. Ludwig
Edmund V. Ludwig, J.

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[12] See pls. br., doc. no. 23 at 4; pls. br., doc. no. 24 at 20-21 n.16; pls. July 8, 2011 email to def. counsel, doc. no. 41, Ex. 2; pls. br., doc. no. 41-1 at 5-7; pls. br., doc. no. 48-1 at 3-4 & n.6; Aug. 30, 2012 letter of pls. counsel, doc. no. 53; pls. br., doc. no 57 at 1, 3-7 & n.3; pls. br., doc. no. 60 at 1-2.

[13] Defendant submits that production of the rulemaking records would be burdensome but does not describe the extent of the difficulty. Plaintiffs say the volume of records is probably modest.